

REMARKS

Applicants thank the Examiner for the recent telephone interview. The claim amendments and following remarks embody the differences, as discussed, between same and the present claims.

New claims 29-30 are added. Claim 29 further claims the subject matter of rejected claim 15. Claim 30 recites properties of the denatured albumin lamina, as disclosed in the original Abstract and in the specification, such as at page 6, lines 19-21. No new matter is added.

Specification Objections

The Abstract is objected to as being overlong and containing more than one paragraph. The Abstract section is replaced with a new Abstract section in compliance with the Examiner's request. ✓

Claim Objections

Claim 27 is objected to under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. The claim is amended to depend from claim 19. Claims 16 and 21 also are amended herein to correct informalities. No new matter is added.

Claim Rejections - 35 USC § 112

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 is amended to more clearly indicate that the claimed method reduces hemorrhage at the lesion site.

Rejections of Claim 14-15, 17 and 19 under 35 U.S.C. § 103(a)

Claims 14-15, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawyer et al. (US Pat. No. 5,749,895), Tayot et al. (US Pat. No. 5,201,745) and Oz et al. (WO 91/04073). The rejection is respectfully traversed.

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The Examiner asserts that Sawyer '895 teaches a solid weldable material, including patches, sheets, films, and/or lamina (Sawyer '895, col. 3, lines 40-50), and that Sawyer '895 further teaches the specific use of an albumin patch (col. 3, line 14, and claim 8).

Sawyer '895 provides no written description or enabling disclosure for albumin patches. The term "albumin" appears only once in the Summary section of this reference: "The preferred biodegradable materials include collagen, gelatin, elastin, fibrinogen, albumin, and composites and add mixtures thereof." (Sawyer '895, col. 3, line 14 (emphasis added).)

The Sawyer '895 specification is devoted to description of a collagen patch, and to methods for making and using same. A thorough review of Sawyer '895 reveals that the reference provides utterly no teaching concerning the properties, manufacture or use of an albumin lamina (i.e., "weldable support structure"). Moreover, "albumin" is not even mentioned in the Detailed Description section. The reference provides no description or enabling disclosure sufficient for one of ordinary skill to make or use an albumin patch in the Sawyer method.

The mere mention of "albumin" in the specification constitutes no more than an invention-broadening assertion to prevent another from using one of the listed biological compounds in place of—or in addition to—collagen.

Applicants point out that physiological responses are unpredictable. As the Examiner is aware, collagen and albumin are found in different tissue types (connective tissue v. blood, respectively); their basic structures are dissimilar (trimeric, largely hydrophobic v. globular hydrophilic); and, one of ordinary skill therefore would have no reasonable expectation of success by substituting a denatured albumin patch for Sawyer's collagen patch—to the extent that one could think to substitute a denatured albumin patch, given the lack of teaching in that regard by Sawyer '895.

One of ordinary skill would not combine the liquid albumin solder of Oz '073 with the solid patch of Sawyer '895 into a single procedure. Claim 14 recites application and irradiation of a liquid solder, and application and irradiation of a denatured albumin patch to the same lesion. Combination of these two steps in one procedure is not suggested by the prior art. In fact, Oz '073 teaches away from the method of pending claim 14.

As the Examiner cites, Oz '073 expressly teaches reduction of thermal damage to tissue in laser soldering lesion repairs. (See Oz '073, page 2, lines 23-28; page 21, lines 20-28.) Another cited reference, U.S. Pat. No. 5,292,362 to Bass, states that:

[H]istological analysis of direct laser welds has shown transmural thermal injury at the site of the weld which adds to the trauma of the injury and surgery. In vascular anastomosis, this can lead to complicating aneurysm formation at the weld site which presents a threat to the healing process and in some cases may lead to internal bleeding and complications associated therewith."

(Col. 3, lines 1-8.) Lastly, Applicants noted in the present application (page 5, lines 15-26; page 13, lines 13-23) that thermal damage was known in the art to be a side-effect of exposure of tissue to laser energy, and that a goal was the avoidance or minimization of such collateral thermal damage at the lesion site.

Given these teachings, the skilled artisan would know that the combination of a laser soldering technique with a subsequent laser welding technique would result in a double dose of laser energy to the target tissue. Such combination runs counter to the prevailing goal of minimizing tissue damage.

The claimed method yields surprising results. The "combination" method of claim 14 has been observed to result in less thermal damage to target tissues than would be expected. Applicants believe that the solder, having been applied at the lesion site, serves as a "buffer" by absorbing energy that otherwise might damage the underlying solid visceral organ. Whatever the mechanism, Applicants have observed that sequential applications of laser energy produce no more thermal damage—and in many cases less tissue damage—than would have been expected.

Rejections of Claim 26-28 under 35 U.S.C. § 103(a)

Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawyer '895, Tayot '745 and Oz '073 as applied to claims 14-15, 17 and 19 above and further in view of Gregory (US Pat. No. 6,372,228). The rejection is respectfully traversed in view of the foregoing remarks regarding Sawyer '895 and Oz '073.

Furthermore, the teachings of Gregory '228 with regard to components added to an elastin patch are not immediately transferable to addition of those components to a denatured albumin lamina. Applicants have noted above the differences between denatured albumin and collagen; similar differences exist between denatured albumin and elastin.

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Gregory '228 fails to teach or suggest that a chromophore or a biologically active agent can successfully be added to a denatured albumin lamina, and the resultant lamina irradiated with energy, without a negative effect on the chromophore/biologically active agent. Other references, such as Bass '362 and Oz '073, deal with native (i.e., non-denatured) albumin and teaches nothing of denatured albumin behavior.

Rejections of Claim 16, 18 and 20-25 under 35 U.S.C. § 103(a)

Claims 16, 18 and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawyer '895, Tayot '745 and Oz '073 as applied to claims 14-15, 17 and 19 above and further in view of Bass '362, Gregory '228 and the instant specification. The rejection is respectfully traversed in view of the foregoing remarks regarding Sawyer '895 and Oz '073.

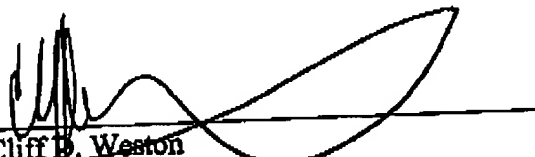
Further to the Examiner's basis for this rejection, Applicants wish to clarify that the specification does not admit that 50%-58% liquid albumin solder solutions are relevant prior art to the claimed use of a 50%-58% solid denatured albumin lamina. One of ordinary skill readily would understand that Bass '362 discusses a liquid solder and not a solid denatured lamina.

As well, the teachings of Gregory '228 that an elastin patch should be as thin as possible so as to be translucent to light energy, and that the lamina thickness should preferably be optimized for the organ to be patched, provides no more than objectives for the present invention to attempt to satisfy. Gregory '228 deals with elastin patches and provides no teaching for the properties of an albumin lamina. A denatured albumin lamina further would inherently have different properties than an elastin patch, owing to the myriad differences between the molecules.

CONCLUSION

For the foregoing reasons, reconsideration and allowance of claims 14-29 of the application as amended is solicited. The Examiner is encouraged to telephone the undersigned at (503) 222-3613 if it appears that an interview would be helpful in advancing the case.

Respectfully submitted,
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